Case Study

# **Transforming MedTech Surveillance:** Achieving 99% Accuracy in Adverse Event Detection with AI-Powered Risk Analytics

## Challenge

A MedTech organization faced significant challenges in post-market surveillance for medical devices. Manual risk identification processes were time-consuming and error-prone, with inefficiencies in synthesizing insights from FDA databases and fragmented data silos.

## Solution

We implemented an end-to-end (E2E) Risk Analytics Platform that automated data collection from FDA databases using intelligent web harvesting. We combined the expertise of life sciences and biomedical instrumentation specialists with AI to create and design a comprehensive knowledge architecture. Advanced analytics were applied to identify adverse events accurately.

## Impact

- Processed over **9 million** records from **20+ data** sources
- Disambiguated data from **70,000+** manufacturers
- Standardized data for **200,000+** Class II and III medical devices
- Identified **4.3 million** adverse events with **99%** accuracy

### About Straive

Straive helps operationalize the data → insights → knowledge → AI journey with its deep domain expertise, process knowledge, and tech and analytics capabilities. Serving a diverse range of industries—including science and research publishing, information services, EdTech, life sciences, and banking and financial services—Straive boasts a global client base spanning over 30 countries. Our strategically positioned resource pool operates across seven countries, including the Philippines, India, the United States, Nicaragua, Vietnam, the United Kingdom, and Singapore, where the company is headquartered.

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